SUMMER– 14 EXAMINATION

Subject Code: **0811** **Model Answer** Page No: 01/ 34

Important Instructions to examiners:

1. The answers should be examined by key words and not as word-to-word as given in the model answer scheme.
2. The model answer and the answer written by candidate may vary but the examiner may try to assess the understanding level of the candidate.
3. The language errors such as grammatical, spelling errors should not be given more Importance (Not applicable for subject English and Communication Skills.
4. While assessing figures, examiner may give credit for principal components indicated in the figure. The figures drawn by candidate and model answer may vary. The examiner may give credit for any equivalent figure drawn.
5. Credits may be given step wise for numerical problems. In some cases, the assumed constant values may vary and there may be some difference in the candidate's answers and model answer.
6. In case of some questions credit may be given by judgment on part of examiner of relevant answer based on candidate's understanding.
7. For programming language papers, credit may be given to any other program based on equivalent concept.

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Q.1. Solve any EIGHT of the following. **16**

i. Define (1MARKS for each definition).

i. Elixir: Elixirs are clear, sweetened, aromatic, hydroalcoholic liquids preparation intended for oral use. May be medicated or non medicated.

ii. Gargles: Gargles are aqueous solution used to prevent or treat throat infection they are usually available in concentrated form with direction for dilution with warm water before use.

ii. Translate Latin terms to English. (0.5 X 4 = 2 Marks).

i. More Dicto = as directed.

ii. Cataplasm = A poultice.

iii. Hora somani = at bed time/Just before sleep.

iv. Ex. lacte = with milk.

iii. Give formulation of wetting solution of contact lens. (0.5 X 4 = 2 Marks)

i. Wetting agent: sodium luryl sulphate.

ii. Thickening agents: cellulose derivative.

iii. Antimicrobial agent: Benzalkonium chioride, chlorohexidine.

iv. Isotonicity adjusters: sodium chloride.

iv. Give any two examples. (0.5 X 4 = 2 Marks)

i. Emulsifying Agents: Gum acacia, Tragacanth, Methyl cellulose, Starch. Etc.

ii. Suspending agents: aluminum hydroxide, Gum acacia, Tragacanth, Methyl cellulose, etc.

v. Give any four properties of ideal suppository base (any four properties 0.5 marks each).

1. It should melt at body temperature.

2. It should keep its shape when being handled.

3. It should release the medicament readily.

4. It should be non-toxic.

5. It should be stable on storage.

6. It should be compatible with large number of drugs.

vi. Differentiate between jellies and poultice. (Any four points 0.5 marks for each).

Sr no.	**Jellies**	**Poultice**
1	Jellies are transparent or translucent non-greasy semisolid preparations meant for external application to the skin or mucous membrane.	Poultices are soft, viscous wet masses of solid substances applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as a counter-irritant.
2	More viscous	Less viscous
3	Used as medicated and for cosmetics purpose.	Used for more medicated.
4	These does not act as carrier of heat	These act as carrier of heat
5	These are applied without warming.	These are applied with warming.
6	They are mainly prepared by natural gums like Gum acacia, Tragacanth, Methyl cellulose	Heavy kaolin is commonly included in the formula
7	**Eg Ichthanmol jelly**	**Eg Kaolin poulitice B.P.C.**

vii. Name any four tests for evaluation of parentral preparation. (0.5 X 4 = 2marks).

1. Sterility test
2. Clarity test
3. Leakage test
4. Pyrogen test
5. Assay.

viii. What are Douches? Give examples (Defination 1mark and Example 1 mark).

Douche is a medicated solution meant for rinsing a body cavity like ear, nose, throat and vagina. Eg. Potassium permanganate douche solution, alum douche. Isotonic sodium chloride solution, etc.

ix. What is Herapath reaction (2 marks).

Oxidation of iodides with quinine sulphate : Quinine sulphate is not freely soluble in water.it is made soluble in presence of sulphuric acid. The sulphuric acid librates hydroiodic acid from the potassium iodide and the hydroiodic acid is partly oxidized by the sulphuric acid, yielding iodine. The iodine, hydroiodic acid and quinine sulphate then combine to form a compound called 'herapathite or iodosulphite of quinine'.

x. Classify paste bases:

i. **Hydrocarbon bases:** ex. Hard and soft paraffin and liquid paraffin.

ii. **Water miscible bases:** ex**.** emulsifying ointments.

iii. **Water soluble base:** ex. Carbopole, PEG.etc.

xi. Give metric equivalent of following. (1 marks each).

1. One teaspoonful = 4 ml.
2. One ounce = 30 ml or 28.8ml/31.2 gm/28.8gm.

xii. Give qualities of good suspension. (0.5 X 4=2marks)

1. It should settle slowly and should be readily re-dispersed on gentle shaking of the container.
2. It should pour readily and evenly from its container.
3. It should be chemically inert.
4. The suspended particle should not form a cake.
5. It should be free from large particles which spoils its appearance.

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Q.2. Solve any FOUR of The following. **12**

a. Differentiate between flocculated and deflocculated suspension. (0.5 X 6 = 3 marks).

Sr. no.	Flocculated suspension	Deflocculated suspension
1	Particles form loose aggregates and form a network like structure.	Particles exist as separate entities.
2	The rate of sedimentation is high	The rate of sedimentation is slow
3	Sediment is rapidly formed	Sediment is slowly formed
4	Sediment is easy to redisperse	Sediment is difficult to redisperse
5	Sediment is loosely packed and does not form a hard cake	Sediment is very closely packed and a hard cake is formed
6	Supernatant liquid is clear	Supernatant liquid is not clear
7	The floccules stick to the sides of bottle.	The floccules do not stick to the sides of bottle.
8	Suspension is not pleasing in appearance	Suspension is pleasing in appearance.

b. What is Posology? Give various formulas of doses for children. (1 mark definition and 2 marks any four formulas).

Posology is the branch of medical science which deals with dosage or quantity of drug. (1 mark)

1. **Dillings formula:** Child Dose = age in years/20 X Adult dose(1 mark)
2. **Clarks formula:** Child Dose = weight in pound/150 X Adult dose (1 mark)
3. **Young's formula: child dose =** Age in years/Age in years +12 X adult dose (1 Marks)
4. **Body surface area formula:** Child Dose = body surface area of child M^2/ avg body surface area of adult 1.73 M^2 X Adult Dose.
5. **Frieds Formula:** Child Dose = age in month/150 X Adult Dose.

c. Comment:

1. Antiperspirant: ((1 marks for description and 0.5 for example).

- It prevents the flow of perspiration to overcome bad smell which is due to bacterial decomposition.
- Antiperspirants contain a substance having **astringent** action on reacting with skin proteins it causes coagulation which is accompanied by swelling at the opening of sweat glands.
- This blocks opening of sweat gland preventing flow of sweat.
- Eg. Aluminium chlorohydrate, any marketed preparation students may write.

2. Deodorant: (1 marks for description and 0.5 for example).

- Deodorant inhibits the formation of bad odour in perspiration by suppressing the growth of bacteria or masks the unpleasant odour.
- Eg. Salicyclic acid, boric acid, zinc stearate, talc and starch powder, any marketed preparation students may write.

d. What do you mean by particulate matter? Describe it's method of testing (Definition 0.5 and limits 0.5 marks and Test 2 marks).

Definition: Particulate matter is unwanted mobile insoluble matter other than gas bubbles present in the given product.

Permitted particulate matters as prescribed in I.P:

Particle size in micro meter (equal to or large than)	**Maximum no of particles per ml**
10	**50**
25	**O5**
50	**Nil**

Testing: (description of any one test 2 Marks)

1. Visual method
2. Coulter counter method
3. Filtration method
4. Light blockage

Visual Method:

- It is an old but reliable method
- The filled containers are examined against strong illuminated screen by holding the neckband rotating it slowly or inverted it to exclude the possibility of foreign particles.
- If any particulate matter is visible, that container is rejected.

Coulter Counter Method:

- The method is based on the principle that increase in resistance is observed between two electrodes, as the particle approaches and passes through the orifice.
- An electrolyte is required to be included in the preparation before its evaluation.
- The particles with diameter below 0.1 /um can be detected by this method.

Filtration method:

- The liquid sample is passed through a filter and the material collected on the surface of the filter
- It is examined under microscope.

Light blockage method:

- It allows a stream of the fluid under test to pass between a bright white light source and photodiode sensor.
- It is possible to detect cross sectional area in this instrument because it blocks the path of light and size of the particle is consider as a diameter of a circle of equivalent area

e. Define the term 'jellies'. Write a short note on its application.(Definition 1 mark)

Jellies are transparent or translucent non-greasy semisolid preparations meant for external application to the skin or mucous membrane.

Application: (2 Marks)

i) **Medicated jellies** are used on mucous membrane and skin for their spermicidal, local anaesthetics and antiseptic properties.

ii) **Lubricating jellies** are used for lubrication of diagnostic equipment such as, surgical gloves, cytoscopes, fingerstalls, catheters, rectal thermometers.

iii) Miscellaneous jellies:

a) **Patch testing:** these jellies are used as a vehicle for allergens which are applied on the skin to check the sensitivity.

b) **Electrocardiograohy:** The jelly is applied on the electrode to reduce the electrical resistance between the patient's skin and the electrode.

f. Define Ointment. Describe fusion method of preparation of ointment (Definition 1 marks and method 2 marks).

Ointments are semisolid preparations meant for external application to the skin or mucous membrane.

Fusion method:

1. Ointment contains number of solid ingredients of different melting points, such as white beeswax, Stearic acid, hard paraffin and cetyl alcohol,
2. **They are melted in decreasing order of their melting point.** This will avoid the overheating of substance having low melting points.
3. The medicament is slowly incorporated to the melted mass, stirred thoroughly until the mass cools down and homogenous product is formed.
4. In case any liquid ingredient or aqueous substance is also incorporated, that should be heated to the almost same temperature as the melted bases.
5. Rapid cooling and vigorous stirring should be avoided to get uniform product and to prevent air entrapment.
6. In order to remove dust or foreign particles from the melted base, it is strained through muslin piece. The clarified liquid is collected in container.

3. Solve any FOUR of the following: 12

a. Enlist the factors influcing dose of drugs. (any six factors 0.5 X 6 = 3))

1. Age.
2. Sex.
3. Body Weight.
4. Body surface area
5. Friquency of administration.
6. Dosage form.
7. Physiological condition.
8. Environmental factor.
9. Disease condition.
10. Tolarance.
11. Iodosyncrysy.
12. Tachyphylaxis.
13. Metabolic disturbances.
14. Synergism.
15. Antagonism.

b. Definition: (1 Mark)

- Diffusible solids are those which are insoluble in water but uniformly dispersed in the vehicle on gentle shaking.
- No need of suspending agent.

Method of Preparation: (2 Marks)

Drug+ soluble material + Vehicle a part from 3/4th

↓ **Smooth cream**

Add remaining vehicle from 3/4th

↓ **Add to measure**

Add other liquid ingredient

↓

Strain through muslin cloth for removal of foreign particles

↓

Make up the volume with remaining vehicle

c. Question can be solved with correction in given manner.

(Find out the quantity of 4% ointment & 15 % ointment which must be added to get 100 g of 10% ointment.)

15 **6 parts of 15%**

10

4 **5 parts of 4 %**

Total: 11 Parts

1. **for 15% : $\frac{6 \times 100}{11}$ = 54.55 gms**
2. **For 4% : $\frac{5 \times 100}{11}$ = 45.45 gms**

d. Definition: (1 Mark)

- EMULSION is a biphasic liquid preparation containing two immiscible liquids which are made miscible by adding emulsifying agent,
- One of which is dispersed as minute globules in to the other.
- The liquid which is converted in to minute globules is called the "Dispersed Phase" & the liquid in which the globules are dispersed is called the "Continuous Phase".

Role of emulsifying agents: (any four roles 0.5 x 4 = 2 Marks)

- **Stabilization of emulsion:**
- **Reduction in Interfacial Tension:**
  - Thermodynamically stabilization
- **Formation of Interfacial Rigid Film:**
  - Mechanical barrier to coalescence
- **Formation of Electrical Double Layer:**
  - Electrical barrier to approach of particles.

e. Difference: (any six points 0.5 X 6 = 3).

Ointments	Paste
○ Contains less amount of solid.	○ Contain large amount of solid.
○ Soft preparation.	○ These are thick and stiff.
○ More greasy.	○ Less greasy.
○ Protective, emollient.	○ Form protective coating.
○ More macerating.	○ Less maceration.
○ Ex. Sulphur ointment	○ Zinc oxide paste BPC.

f. Definition: (1 Mark)

Cosmetics: The articles intended to be rubbed, poured, sprinkled or sprayed or introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance.

Ideal properties of face powder :(any four properties 0.5 X 4 = 2 Marks)

1. It should be very fine and should not have any gritty particles.
2. It should be non-toxic.
3. It should be non-irritant to the skin.
4. It should look natural.
5. It should not remove from the skin immediately after its application.
6. It should be stable both physically and chemically.
7. It should have good absorbing property.
8. Its ingredients should be evenly distributed.
9. It should remove shine from the face.
10. It should stick to the face and should not dust off in a few minutes

4. Solve any FOUR of the following: 12

a. Total parentral nutrition: (Definition=1 M, Formula=1M, application=1M)

- Total parenteral nutrition (TPN), is the practice of feeding a person intravenously, bypassing the usual process of eating and digestion.
- The person receives nutritional formulas containing salts, glucose, amino acids, lipids and added vitamins.
- It is provided when the gastrointestinal tract is nonfunctional because of an interruption in its continuity or because its absorptive capacity is impaired.
- Long-term TPN is occasionally used to treat people suffering the extended consequences of an accident or surgery or digestive disorder.
- TPN has extended the life of children born with nonexistent or severely deformed guts.

- The preferred method of delivering TPN is with a medical infusion pump.
- A sterile bag of nutrient solution, between 500 mL and 4 L is provided.
- The pump infuses a small amount (0.1 to 10 mL/hr) continuously in order to keep the vein open.
- This should be done over 12 to 14 hours rather than intermittently during the day.
- TPN requires water (30 to 40 mL/kg/day), **energy (30 to 60 kcal/kg/day, depending on energy expenditure)**, amino acids (1 to 2.0 g/kg/day, depending on the degree of catabolism), essential fatty acids, vitamins, and minerals
- Children who need TPN may have different fluid requirements and need more energy (120 kcal/kg/day) and amino acids (2.5 to 3.5 g/kg/day).

b. Definition: (1 Mark)

When two or more substance mixed together, a physical change takes place and an undesirable product is formed.

Types of Physical Incompatibility: (0.5 X 4 = 2 Marks)

1. Immiscibility.
2. Insolubility.
3. Precipitation.
4. Liquefaction.

1. Immiscibility.

Rx

Castor oil .....15 ml

Water ..... 6.0 ml

Make an emulsion

2. Insolubility:

Rx

Phenacetin ..... 3 g

Caffeine ..... 1 g

Orange syrup ... 12 ml

Water ..... 90 ml

3. Precipitation:

Rx

Tincture of benzoin ..... 5.0 ml

Glycerin ..... 15 ml

Rose water ..... 100 ml

4. Liquification:

Rx

Menthol ..... 5 g

Camphor ..... 5 g

Ammonium Chloride ..... 30 g

Light Mg carbonate ..... 60 g

Prepare a powder

c. Sterility testing: (principle=0.5M, sampling = 1 M, method =1M, result = 0.5).

- The test for sterility is done by detecting the presence of viable forms of bacteria, fungi & yeast in parental preparations.

Principle: (0.5M)

- The test s based on the principle that if bacteria or fungi are placed in a medium which provides nutritive material & water & kept a favorable temperature the organism will grow & their presence can be indicated by turbidity in the clear medium.

Selection of sample size: (1M) (any one table)

Number of items in batch	Minimum number of items recommended to be tested
Injectable preparation not more than 100 containers	10% or 4 containers whichever is the greater
More than 500 containers	2% or 20 containers whichever is the less

Quantity in each container	**Minimum quantity to be used**
Less than 1ml	Total contents of a container
1ml or more but <4ml	½ content of a container
4ml or more but less than 20ml	2ml
20 ml or more but <100ml	10% of content f the container unless otherwise specified in monograph
100ml or more	NLT ½ the content of a container unless otherwise specified in the monograph

Method of testing: (0.5M)

- **Membrane filtration method:-** The membrane filtration method is performed in following cases :
  - An oil or oily preparation.
  - An ointment that can be put into solution.
  - A soluble powder or a liquid that posses bacteriostatic & fugistatic properties.
  - Liquid products where the volume in container is 100 ml or more.

- It involves the filtration of sample under test through a membrane filter having porosity of 0.45 u & dia. 47 mm
- After filtration, membrane is removed aseptically & divided into 2 parts.
- The first part is transferred into 100ml of culture media meant for fungi & incubated at 20^{o} to 25^{o}C for NLT 7 days.
- The other half part is transferred into 100ml of fluid thioglycollate medium & incubated at 30 to 35^{o}C for NLT 7 days.
- Observe the growth in media.

- **Direct inoculation method: -**
  - In this method the specified qty of sample under test is drawn aseptically from container & transferred into vessel of culture medium.
  - Mix the liq. With the medium & incubate for NLT 14 days
  - Observe the turbidity in media.

Result & interpretation: (0.5 M)

- No evidence of growth – passes the test for sterility.
- Evidence of growth – Re-testing

d. Definition: (1 mark)

Poultices are soft, viscous wet masses of solid substances applied to the skin for their fomentation action in order to provide relief from pain or reduce inflammation or to act as a counter-irritant.

Rx

Heavy kaolin finely sifted and dried at 100^{0}C ----- 527 g
Boric acid ---------- 45 g.
Thymol ---------- 0.5 g.
Peppermint oil ---------- 0.5 ml
Methyl salicylate ---------- 2 ml.
Glycerin ---------- 425 g.

Send 20 gm

Direction: to be used as directed.

Method of Preparation: (2Marks)

- Sieve kaolin & Boric acid through a sieve no. 180.
- Mix the Heavy kaolin & Boric acid with glycerin to form a smooth paste in a mortar.
- Transferred to a heat resistant glace jar protected suitable and heat at 120^0C for one hour in hot air oven with occasional stirring.
- Dissolve thymol in methyl salicylate and Peppermint oil.
- At this solution to cooled mixture and mix thoroughly.
- Transfer it to suitable container closes it tightly and labels it.

e. Dispensing:

I. Eutectic Mixture: (1.5 Marks):

- When two or more substances are mixed together they liquefy due to the formation of new compound which has a lower melting point than room temperature such substances are called as eutectic mixtures.

Method of Dispensing:

- The can be dispensed in separate set of powders with direction that one set of each kind shall be taken as a dose.
- Equal amount of any inert absorbent like Light Magnesium carbonate, kaolin, starch, lactose, calcium phosphate may be mixed with eutectic substance and then blended together.

Rx

Menthol	5 parts
Camphor	5 parts
Ammonium chloride	30 parts
Light Magnesium carbonates	60 parts

Prepare a powder, send 20 g.

II. Explosive Mixture: (1.5 marks)

- When an oxidizing substance such as potassium chlorate is mixed with reducing substance such as tannic acid there are chances of violent explosion which may leads to serious consequences.

Method of dispensing:

- The later approach avoids physical contact between interacting substances.
- Mixing using mortar pestle is not advisable.
- Spatulation or tumbling are convenient methods.

Rx

Potassium chlorate	0.6g
Tannic acid	0.3g
Sucrose	0.3g

f. Definition: (1 mark)

Displacement Value: It is the amount of medicament required to displace one part of suppository base.

Significance: (2 Marks)

The volume of suppositories from a particular mould will be constant but the weight will vary because the densities of the medicaments usually differ from the density of the base, and hence the density of the medicament will affect the amount of the base required for each suppository.

Q.5. Solve any FOUR of following: **12**

a. **Definition**: **(1 Mark)**

Parenteral preparations are those pharmaceutical products that are given by other than oral routes.

Steps Involved: (2Marks)

i. **Cleaning** of containers, closures and equipments: All the containers, closures and equipments which are required for the preparation are cleaned thoroughly with detergent and washing is done with tap water followed by distilled water and finally rinsed with water for injection. Rubber closures are washed with hot solution of 0.5% sodium pyrophosphate in water, than washed with water and rinsed with water for injection.

ii. **Collection of materials:** Ingredients of parental preparation are weighed and collected in preparation room all the ingredients has to be of pharmacopial standards Water for injection which is free from pyrogen has to be used for preparation.

iii. **Preparation of parenteral product:** The pharmacist should decide the order of mixing and exact method of preparation to be followed before preparing the parenteral product, the parental preparations must be prepared under strict aseptic conditions.

iv. **Filtration:** The parental solution so formed is passed through bacteria proof filter, the primary objective is to clarify the solution by removing foreign particles, if the preparation has to be sterilized by filtration than it has to be done in strict aseptic conditions before it is transferred into final container and sealed.

v. **Filling the preparation in final containers:** The filtered product is filled into final container, which are cleaned dried and sterilized on small scale hypodermic syringe and needle are used and on large scale automatic

filling machine are used. The sterile powders are filled into the container by individual weighing or by using automatic or semi automatic devices. The filling operation is carried under strict aseptic precautions.

vi. **Sealing the container:** Sealing should be done immediately after filling. Ampoules are sealed manually on a small scale, but on a large scale ampoule sealing machine is used. Vials and transfusion bottles are sealed by closing its opening with rubber closures, and then crimping of aluminum cap is done manually or mechanical means.

vii. **Sterilization:** The parental preparation should be immediately sterilized after sealing any method of sterilization can be used depending on nature of medicaments present in the preparation.

viii. **Evaluation of parentral preparations:** The finished products are subjected to following tests in order to maintain quality control a)sterility test b)clarity test c)leakage test d) pyrogen test e) essay.

b. Dispensing of preparation:

Rx,

Sodium Salicylate……0.9 grams

Caffeine Citrate……0.6 grams

Water to make…… 30.0 ml.

Prepare a draught

Label: To be taken at once

In above formulation there is a chemical incompatibility due to the chemical interaction among the ingredients. (**1 marks)**

Caffeine citrate is a mixture of equal weight of caffeine and citric acid. The citric acid present in caffeine citrate react with sodium salicylate to liberate salicylic acid which gets precipitated. If caffeine is used instead of caffeine citrate it forms a soluble complex with sodium salicylate. Hence substitute caffeine citrate with half as much caffeine as that of caffeine citrate to form a clear mixture. **(2Marks)**

c. Dusting Powder:

Dusting powders are meant for external application to the skin and are generally applied in a fine state of sub division to avoid local irritation; hence dusting powders should be passed through sieve no 80 to enhance their effectiveness. (**1mks**).

Dusting powders types:

i. Medical Dusting powders.
ii. Surgical Dusting powders.

i. Medical dusting powders are used mainly for superficial skin conditions, whereas. Medical dusting powders must be free from pathogenic micro organisms.
ii. Surgical dusting powders are used in body cavities and also on major wounds as a result of burns and umbilical cords of infants surgical dusting powders must be sterilized before their use.

Dusting powders are generally prepared by mixing of two or more ingredients; starch talc kaolin is used as one of the ingredient as talc and kaolin are chemically inert. The dusting powders are used for antiseptic, astringent, absorbent, antiperspirant and antipuritic action. There are dispensed in sifter top container or aerosol container they have to be protected from infants as the inhalation of fine powder ingredients by infants may lead to pulmonary inflammation. **(2 Marks)**

d. Shampoo:

Shampoos may be define as preparation containing surface active agents which are used to remove dirt grease and debris from the hair scalp and other part of body without affecting the natural gloss of hair **(1mark)**

Various additives used in formulation of shampoos

1) **Conditioning Agent:-** used to lubricate the hair & improve the texture of hair & it reduces the fluffiness & make the hair soft & shiny.
   e.g. Lotion & its derivatives, Glycerin, PG
2) **Thickening Agents:-** Use to increase the viscosity of shampoo & provide desired consistency.
   e.g. Polyvinyl alcohol, Methyl cellulose, Na Alginate
3) **Solubilizig Agent :-** Used to solubilize poorly soluble subs.
   e.g. ethyl alcohol, glycerol, PG.
4) **Opacifying Agents:-** used to make shampoo opaque.
   e.g. glycerol, glyceryl stearate, stearyl alcohol.
5) **Preservatives:-** used to preserve the shampoo against bacteria or mould.
   e.g. Methyl Paraben, Propyl Paraben **(2 mks)**

e. Short Note:

Glycero-gelatine base is a mixture of glycerin and water which is made stiff by the addition of gelatin the base may be used for preparing all type of suppositories but it is particularly used in making pessaries. The suppositories are translucent which tend to dissolve or disperse slowly in the body cavity and release the medicament **(1 mks)**

To avoid incompatibility reactions any one of the two types of gelatin used as suppository base Pharmagel A which is acidic in nature and used for acidic drugs having iso-electric point(7-9)

Pharmagel B which is alkaline in nature and used for alkaline drugs having iso-electric point (4.7to5) **(1mks)**

Disadnvantages: (any two disadv =1Mark)

i. The solution time depends on the content and quality of glycerin
ii. Gelatine is incompatible with many drugs such as tannic acid ferric chloride gallic acid ect
iii. There are chances of bacterial and mould growth therefore preservative has to be added
iv. The base is hydroscopic and hence special storage condition is required.
v. They have laxative action
vi. They are more difficult to prepare and handle.

f. Definition:

Pyrogens are the metabolic products of living or dead microbes they cause rise in body temperature upon injection the parenteral preparation has to be pyrogen free. **(1mks)**

Sham Test: Pyrogen testing done on rabbit: The test involves the measurement of rise in body temp. of rabbit following intravenous injection of a sterile solution of a substance being examined. Three healthy rabbits ,each weighing not less than 1.5 kg are selected. They are kept on balanced diet.& are not showing any loss in body weight .The solution under test is injected slowly through ear vein in a volume of 0.5 to 10 ml/body weight. Record the temperature of each rabbit in an interval of 30 mins for three hrs. after the injection. The difference between initial temp & the maximum recorded as response.

If no rabbit shows an individual rise in temperature of 0.6 °C or more above its respective control temperature, and if the sum of the 3 temperature rises does not exceed 1.4 °C, the tested material meets the requirements for the absence of pyrogen. If 1 or 2 rabbits show a temperature rise of 0.6 °C or more, or if the sum of the temperature rises exceeds 1.4 °C, continue the test using 5 other rabbits. If not more than 3 of the 8 rabbits show individual rises in temperature of 0.6 °C or

more, and if the sum of the 8 temperature rises does not exceed 3.7 °C, the tested material meets the requirements for the absence of pyrogen.

or

LAL test is used for the detection and quantification of bacterial endotoxins.

Limulus amebocyte lysate (LAL) is an aqueous extract of blood cells (amoebocytes) from the horseshoe crab, Limulus polyphemus. LAL reacts with bacterial endotoxin or lipopolysaccharide (LPS), which is a membrane component of Gram negative bacteria.

The solution of endotoxins containing preparation is added to the lysate derived from heamolymph cells of horseshoe crab (limulus polymhemus). The result of the reaction is turbidity or precipitation or gelation of the mixture. This is used as a quantitative measure to estimate the endotoxin content. The rate of reaction depends upon conc. of endotoxins, pH, temperature and presence of clotting enzyme system and clottable proteins from lysate **(any one method 2 mks)**

Q.6. Solve any FOUR of following: **12**

a. Dispensing:

Quantity for 10 gms.

Rx

Citric acid	1.14gms
Tartaric acid	2.57gms
Sodium bicarbonate	4.85gms
Sucrose	1.425gms (1mks)

Prepare effervescent granules, send 10 gm.

Methods of preparing effervescence granules: (1 Mark)

Heat method:.

Wet method:

Method of preparation (Heat method) (any one method 2mks)

A large porcelain dish is placed on a water bath, with as much of the dish as possible exposed to the water or steam

2)The dish must be hot to ensure rapid liberation of water of crystallization from citric acid. If heating is delayed until powder is placed in the dish, the water is liberated slowly as the temp. Rises, but much is lost by evaporation.

3) The ingredients are powdered, sieved, weighed & mixed. They are then placed in dish & pressed down with spatula until the mixture has been formed a loose cake or damp coherent mass.

4) The mixture is passed through sieve No. 8- 14 initially. Dry the granules at 60 ° c Then they are again passed through sieve no. 14-20. to collect reqd. Fraction

(Wet method) The mixed ingredient are moistened with a non aqueous liquid (alcohol) to prepare the coherent mass which is passed through a no 8 seive and dried in oven at the temperature not exceeding 60oC the dried granules are passed through sieve no. 14-20. to collect reqd. Fraction

b. Short Note on Cachet:

Definition: - Cachets are the solid Unit dosage form of drugs.

These are moulded from rice paper, used to enclose nauseous or disagreeable Powders and are available in different sizes to hold drugs from 0.2 to 1.5 gm of powders. **(1 Mark)**

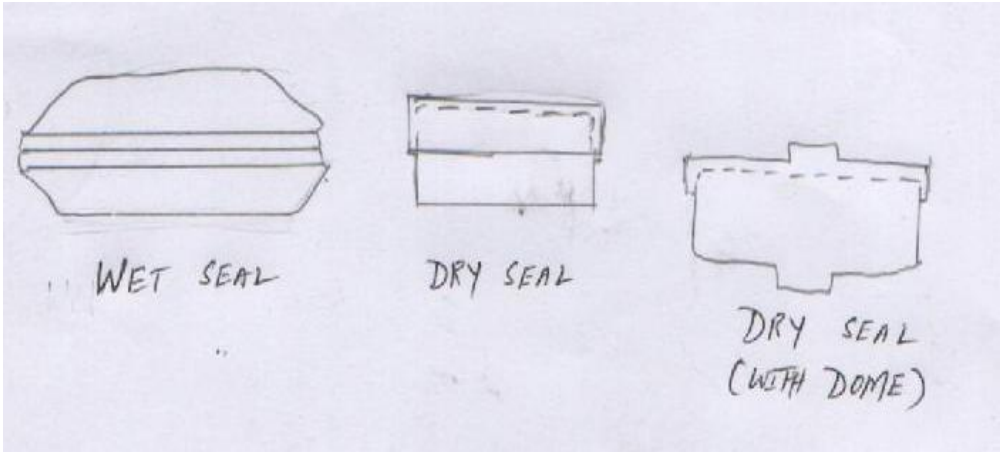
Types: (2 Mark)

i. Wet sealed:

- A wet seal cachet is made up of two similar convex halves having flat edges.
- The weighed quantity of powdered drug is placed in one half, the edges of the other half are moistened with water and placed exactly over the first half containing the drug.
- The flat edges of both the halves are pressed together in order to seal it perfectly.

ii. Dry sealed:

- Dry seal cachets consists of two halves, the upper half and the lower half.
- The diameter of the upper half is slightly larger than the lower half. The powdered drug is filled in lower half and upper half is fitted over it.
- The filled cachets are then sealed in a machine by pressing the two halves, removed and packed in boxes.



Advantages: **(any two adv 0.5 mark)**

1) It can be made easily made no complicated machines required
2) They disintegrate quickly in stomach
3) The drug can be easily dispense
4) Large doses of drug can be swallowed by using cachets

Disadvantages: **(any two disadv 0.5 Mark)**

1) They have to be soften before swallowing
2) They are easily damaged
3) They cannot protect drug from light and moisture
4) The shell is very fragile
5) They cannot be manufactured on large scale (1/2 mks for any adv)

c. Factors for selection of ointments base:

A. Dermatological factors:

1. Absorption & penetration
2. Effect on skin function
3. Miscibility with skin secretion
4. Compatibility with skin secretions
5. Freedom from irritant effect
6. Emollient properties
7. Ease of application and removal

Absorption & penetration:Absorption indicates entry of medicament into the blood stream, systemic absorption.Penetration indicates passage of vehicle along with medicament through the skin, cutaneous absorption.The substances soluble both in 0il & water are readily absorbed.

Effect on skin function: Greasy bases may interfere with skin functions like heat radiation& sweat excretions, hence are skin irritant.Water soluble bases & o/w emulsion bases provides cooling effect rather than healing effect. This bases readily mix with skin secretions.

Miscibility with skin secretion: Water miscible & emulsion bases are miscible with skin secretions readily thereby releasing medicament rapidly & completely as compared to greasy bases.

Compatibility with skin secretions: The ointment bases should have a pH around 5.5 which is the average pH of the skin secretions.Neutral ointment bases are preferable since does not cause irritation

Freedom from irritant effect: The ointment bases used should be non-irritant.Greasy bases cause irritation and may cause edema.

Emollient properties: Ointment bases used should possess emollient properties that should be able to keep the skin moist. Humectants like glycerin and propylene glycol keep the skin surface moist and soft. Wool fat, lard and paraffin keep the skin soft by preventing rapid loss of moisture from the skin.

Ease of application and removal: Ointment bases used should be easily applicable and easy to remove from the skin. Stiff and sticky ointment bases are not suitable because they may cause damage to the newly formed tissues of the skin. o/w type emulsion bases are preferable as they are easy to apply & remove from skin.

B. Pharmaceutical factor:

1. Stability
2. Solvent properties
3. Emulsifying properties
4. 2Consistency

Stability: The fats and oils are liable to undergo oxidation. This can be prevented by adding antioxidant ointments containing liquid paraffin may get oxidized on prolong storage. O/w type emulsion bases are liable to microbial growth and needs a proper preservative. Emulsified bases are liable to phase separation due to improper formulation or under the influence of temperature

Solvent properties; Medicaments insoluble in the ointment bases are mixed in finely powdered form for uniform distribution, Phenol in solid form is quite caustic and cause blisters in a finely divided form in an ointment base. Hence, a base consisting of a mixture of hard and soft paraffins, beeswax and lard is recommended for phenol, which keeps phenol in solution form.

Emulsifying properties: Hydrocarbon bases can absorb only a small amount of water in comparison to animal fats which can absorb large quantities of water. Wool fat is included for the preparation of base meant for eye ointments. Similarly cetrimide emulsifying ointment is capable of absorbing considerable amount of water forming o/w creams

Consistency: It should be of suitable consistency. It should neither be too hard nor too soft. Consistency is such that it withstands wide variation in temperature conditions. The consistency of an ointment can be adjusted by using of high melting point substances like hard paraffin, beeswax in soft ointments and low melting point substances like liquid paraffin in hard ointments respectively.

d. Suppository bases are divided into three types. (1mks for classification and 1 marks for each classs description))

A. Oleaginous bases:
   1. Cocoa butter.
   2. Emulsified cocoa butter.
   3. Hydrogenated oils.

B. Hydrophilic bases/ aqueous bases:
   1. Glycero-gelatin base.
   2. Soap-glycerin base.
   3. Polyethylene glycol.

C. Emulsifying/Synthetic bases:
   1. Witepsol
   2. Massa estarinum
   3. Massuppol.

Fatty bases:

Cocoa butter:

- **Source:**
  - Cocoa butter is fat obtained from the roasted seed of Theobroma cocoa.
- **Properties:**
  - At room temperature it is a yellowish, white solid having a faint, agreeable chocolate like odour.
  - Chemically, it is a triglyceride (combination of glycerin and one or different fatty acids) primarily of oleopalmitostearin and oleodistearine.
  - It melts at 30 - 35^0C,
- **Advantages**:
  - Melting just below the body temperature.
  - Maintaining its solidity at usual room temperatures.
  - Readily liquefy on heating and solidify on cooling.
- **Disadvantages:**
  - Exhibits marked polymorphism.
  - Rancidity.
  - Stick to mould.
  - Leakage from body cavity.
  - Costly.
  - Immiscibility with body fluid.
  - Chloral hydrate or lactic acid liquefies it.

Emulsified theobroma oil:

- It is used as base when large quantities of aqueous solution are to be incorporated.

Hydrogenated oils:

- These are obtained by hydrogenation of various vegetable oils.
- These include hydrogenated vegetable oils, such as coconut, palm kernel, cottonseed, peanut, fractionated palm kernel oil etc.

- **Advantages:**
  - Hydrogenation increases resistance to oxidation.
  - Increases chemical inertness,
  - Lubrication not required.
- **Disadvantages:**
  - Become brittle on rapid cooling.
  - Sedimentation of added substance take place.

Hydrophilic bases/Aqueous bases:

Glycerogelatine base;

- It is a mixture of glycerin and water which is made stiff by the addition of gelatin.
- Type of gelatin bases: to avoid incompatibility.
  - Type A or Pharmagel A: acidic in nature and used for acidic drugs having iso-electric point (7-9)
  - Type B or Pharmagel B: alkaline in nature and used for basic drugs having iso-electric point (4.7-5.0).
- Used for vaginal suppositories.

Advantages:

- It melts at body temperature.
- It mix with body fluid.
- Not rancid.
- It can be used to prepare suppositories using boric acid, chloral hydrate bromides, iodides, iodoform opium etc.

Disadvantages:

- Difficult to prepare and handle.
- Chance of bacterial growth.
- Hygroscopic in nature. (become hard on drying and soft in cont with moisture)
- Laxative in action.
- Incompatible with tannic acid, gallic acid, ferric chloride etc

Soap-glycerin base:

- In this base glycerin is replaced by soap or sodium stearate.
- This makes the base hard.

Polyethylene glycols:

- These are commonly known as carbowax.
- These are available in solid, liquid or semi-solid state depending on molecular weight.

Emulsion Bases:

Witepsol:

- They consist of triglycerides of saturated vegetable fatty acid with varying percentage of partial esters.
- A small amount of beeswax is added for use in hot climate.
- It should not be cooled rapidly as it become brittle and fracture.
- Lubrication is required.

Massa estarinum:

- It is a mixture of mono, di and triglycerides of saturated fatty acids having the formula $C_{11}H_{23}COOH$ to $C_{17}H_{35}COOH$.
- This is also known as adeps solidus.
- It is a white, brittle, almost odourless and tasteless solid.
- It has a m.p. 33.5 to 35.5^0C.
- They are available in various grades but grade B is commonly used in dispensing.

Massuppol:

- It consists of glyceryl esters mainly of lauric acid to which small amount of glyceryl monostearate has been added to improve its water absorbing capacity.

e. Definition:

Syrup is a concentrated or nearly saturated solution of sucrose in purified water the concentration of sucrose is 66.7% w/w there can be medicated syrup or flavored syrup. **(1mks)**

Method of preparation

1) By **simple solution** method e.g. simple syrup or ginger syrup Add sucrose to purified water and heat to dissolve sucrose with occasional stirring cool and than add water to make required weight.

2) By process of **extraction** e.g tolu syrup Add boiling purified water to tolu balsam, cover the vessel lightly and boil the content for half an hour stirring frequently add purified water to adjust the specific weight ,cool and filter the solution add sucrose and dissolve by add of heat.

(3)Syrups made by **chemical reaction** e,g comp syrup of ferrous phosphate In this preparation the reaction takes place between iron wire and phosphoric acid result in formation of ferrous phosphate reaction also takes place between calcium carbonate potassium bicarbonate and phosphoric acid resulting in formation of corresponding phosphate salts after the reaction is complete add sucrose and flavoring agent than adjust the volume with purified water.

(2 mks for any 2 methods)

f. Cracking:

Cracking means the separation of two layers of dispersed phase and continuous phase, due to the coalescence of dispersed phase globules which are difficult to redispers by shaking (1 Mks)

The following factors results in the cracking of emulsion.

(0.5 X 6 factors = 3 marks)

i) Decomposition of the emulsifying agent

ii) Addition of a solvent which dissolves both the phases

iii) High temperature and change in pH.

iv) Addition of opposite types of emulgents

v) Growth of micro – organism

vi) Extensive creaming. (2 Marks)

Decomposition of emulsifying agent:

- When acid is added to alkali soap emulsion it causes decomposition of emulsifying agent & thus leading to cracking of emulsion.

Addition of common solvent:

- Addition of common solvent in which both disperse & continuous phase are soluble forms one phase system & destroys the emulsion.
- Eg. Turpentine, soft soap & water are soluble in alcohol.

Change in Temperature:

- Increase in temperature leads to reduction in viscosity; encourage creaming thus leads to cracking. Low temperature causes freezing of water content.

Addition of emulsifying agent of opposite type:

- **Soaps of monovalent** metal produces **o/w** emulsion,& Soaps of **divalent metal** produces **w/o** emulsion. But addition of monovalent soap to divalent soap emulsion & viceversa may leads to cracking.

Growth of microorganism:

- Preservative should be present otherwise bacteria may destroy emulsifying agent & cause cracking.

Extensive reaming cause creaming: